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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|-----------------------------|---------------------|------------------|
| 10/599,953   | 10/13/2006  | Clifton D. Crutchfield      | 121934.00002        | 7175             |
| 34282 7590 09/02/2010<br>QUARLES & BRADY LLP<br>ONE SOUTH CHURCH AVENUE, SUITE 1700<br>TUCSON, AZ 85701-1621 |             |                             |                     |                  |
| EXAMINER<br>SKORUPA, VALERIE LYNN  |             |                             |                     |                  |
| ART UNIT<br>3771   |             | PAPER NUMBER                |                     |                  |
| NOTIFICATION DATE<br>09/02/2010  |             | DELIVERY MODE<br>ELECTRONIC |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

# Office Action Summary

**Application No.**

10/599,953

**Applicant(s)**

CRUTCHFIELD, CLIFTON D.

**Examiner**

VALERIE SKORUPA

**Art Unit**

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 and 5-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

This office action is responsive to the amendment filed on June 11, 2010. As directed by the amendment: claims 1, 7, 12, 13, and 17 have been amended, claim 4 has been canceled, and no new claims have been added. Thus, claims 1-3 and 5-20 are presently pending in the application.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 3, 5, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield (US Patent No. 4,765,325).
3. As to claim 1 and 3, Crutchfield discloses a method for fit testing a respirator 10 having a breathing port 24, comprising the steps of: placing the respirator 10 on a test subject's face (col. 4, ln. 7-9), having the test subject hold his breath (col. 4, ln. 27), closing a breathing port 24 of said respirator 10 (col. 4, ln. 27-30), thereby initiating a controlled negative pressure testing protocol when intra-respirator pressure substantially equals ambient pressure (Even though Crutchfield's method comprises applying the vacuum while the patient is allowed to breath normally before having the subject hold his breath and close the breathing port (col. 4, ln. 13-14), this does not seem to be a criticality. It appears that Crutchfield's test begins after the patient exhales

and holds his breath when the breathing port is closed and the negative pressure starts building inside the mask. Therefore, it would have been obvious to run the vacuum just after the breathing port is closed since it is not needed before the test begins. Thus, since the breathing port is closed after the subject holds his breath, the pressure at this time would be substantially equal to ambient pressure (col. 8, ln. 53-63)), producing and maintaining a predetermined level of vacuum in the respirator 10 (col. 4, ln. 30-41), and measuring a flow rate of air necessary to maintain said level of vacuum (col. 5, ln. 4-12). Crutchfield lacks detailed description as to the limitation that a switch is activated that closes the breathing port. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the respirator of Crutchfield to include a switch to activate closing of the valve 42 to close off the breathing port 24 since switches are well known in the art for activating valves and it appears that Crutchfield's method would perform equally well with the inclusion of a switch to close the breathing port. Furthermore, having the test subject activate the switch at the moment intra-respirator pressure equals ambient pressure is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have to test subject activate the switch in order to reduce the number of people required to perform the test since it appears Crutchfield's method would perform equally well with the test subject activating the switch to close the breathing port.

4. As to claim 2, Crutchfield discloses that the test subject inhales before holding his breath (the subject is allowed to breath normally before exhaling and holding his breath, col. 8, ln. 44-47).

5. As to claim 5, Crutchfield discloses monitoring internal respirator pressure (via pressure transducer 32 (Fig. 3, col. 8, ln. 13-18).

6. As to claim 17, The modified apparatus of Crutchfield discloses the claimed invention (as discussed in claim 1 above) including a leak rate analyzer (Fig. 3) comprising an air-pressure transducer 32, a vacuum source 38, an air-flow measuring device 30.

7. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of DuBois (US Patent No. 3,948,589).

8. As to claim 6, Crutchfield discloses the claimed invention except that the breathing port is closed by generating an air pressure sufficient to move a diaphragm within the breathing port into an air-sealing position. However, DuBois teaches the use of a squeeze bulb 94 to generate a pressure sufficient to move a diaphragm 72 (col. 5, ln. 41-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield to include closing the port by generating a pressure sufficient to move a diaphragm as taught by DuBois in order to provide a suitable means for manually controlling opening and closing of breathing port since it appears that Crutchfield's method would perform equally well with this modification.

9. As to claim 8, the modified method of Crutchfield discloses that release of the switch results in the opening of the breathing port (see col. 5, ln. 54-60 of DuBois).

10. Claims 7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of Zocca et al. (US Patent Publication 2003/0172925), and further in view of Spinello (US Patent Publication 2003/0100888).

11. As to claim 7, Crutchfield discloses exhausting air from the respirator (via vacuum) to generate and maintain a desired negative challenge pressure inside the respirator for a specified test period, whereby the challenge pressure is held constant (col. 4, ln. 30-41), but does not disclose that the vacuum source utilizes a piston or that measurement of a piston displacement rate yields a direct measure of an air leakage rate into the respirator. However, Zocca teaches a vacuum source which utilizes a piston 244 (paragraph [0058]). Furthermore, Spinello teaches measuring a flow rate based on displacement of a piston (paragraph [0050]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield so that the vacuum source includes a piston and measurement of a piston displacement to yield the air leakage rate as taught by Spinello, in order to provide a suitable alternative means for creating a negative pressure within the mask and an accurate and easy means for measuring the leakage rate, respectively, since it appears that Crutchfield's method would perform equally well with this modification.

12. As to claim 9, the modified method of Crutchfield discloses that internal respirator pressure is progressively reduced to the negative challenge pressure in order to limit challenge pressure overshoot (col. 4, ln. 30-41 of Crutchfield).

13. As to claim 10-16, the modified method of Crutchfield discloses the claimed invention including a vacuum source 38 (Fig. 3 of Crutchfield), but does not disclose

adjusting a motor control logic of the vacuum source according to the claimed iterative algorithm. However, choosing an algorithm for control of a motor is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield to include the iterative algorithm in order provide a suitable means for controlling the performance of the vacuum source since it appears that Crutchfield's method would perform equally well with this modification.

14. As to claim 12, the modified method of Crutchfield discloses the claimed invention except for storing pressure and leak flow rate information in an array during a track phase of the fit test; and applying a post-test analysis algorithm to integrate all acceptable leak measurements while excluding those segments of the track phase that do not meet predetermined pressure criteria or identifying periods or bins of acceptable pressure tracking, determining whether an acceptable number of such bins was produced during the fit test; and integrating the flow rate measurements associated with each bin to determine the mean respirator leak rate for that specific test, wherein test quality is quantified as a function of the number of acceptable pressure bins recorded during the fit test, said function comprises: if bins > 3, then report measured leak rate; else if 3 > bins > 0, then report estimated leak rate; else if bins = 0, then report retry test, and wherein said specified range of said challenge pressure comprises + 10%. However, choosing a method for analyzing post-test data is a design consideration. Furthermore, taking acceptable values of a test run and integrating the measurements to get a mean value is a well known procedure for evaluating the performance of a test. Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the method of Crutchfield to include the steps of analyzing the data post-testing in order to evaluate the overall performance of the test since it appears that Crutchfield's method would perform equally well with a post-test analysis.

15. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of Zocca et al. (US Patent Publication 2003/0172925).

16. Crutchfield discloses the claimed invention including a by-pass orifice 52 present in tubing 54 between the vacuum source and the leak rate analyzer (col. 9, ln. 37-40), but lacks detailed description as to the limitation that the air-flow measuring device and said vacuum source comprise a piston controlled by a stepper motor. However, Zocca teaches a piston 244 (Fig. 12c) used in a vacuum source that is controlled by a stepper motor 247 (paragraph [0118], ln. 1-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a stepper motor controlled piston as the vacuum source in order to provide a suitable means for pumping air out of the respirator since it appears that Crutchfield's apparatus would perform equally well with a stepper motor controlled piston as the means for withdrawing air from the inside of the mask.

#### ***Response to Arguments***

17. Applicant's arguments filed June 11, 2010 have been fully considered but they are not persuasive.

18. Applicant argues, on page 8 of the Remarks, that Crutchfield does not disclose closing the breathing port when intra-respirator pressure substantially equals ambient



pressure since Crutchfield's method has the patient exhale (creating a positive pressure within the mask) before closing the breathing port. However, the argument is not well taken because the modified method of Crutchfield, as described above, includes having the patient exhale and then hold his breath while the breathing port is still open. Therefore, it appears that when the subject's breath is held, the pressure within the mask would go substantially to ambient pressure. Since the breathing port is closed while the subject is holding his breath, it seems that the step of closing the breathing port when intra-respirator pressure is substantially equal to ambient is met.

### ***Conclusion***

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **VALERIE SKORUPA** whose telephone number is

(571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/VALERIE SKORUPA/  
Examiner, Art Unit 3771

/Danton DeMille/  
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